

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	Continuation of 09/661,836
		Filing Date	December 4, 2001
		First Named Inventor	James Ronald Lawter
		Group Art Unit	
Examiner Name			
Attorney Docket Number	ORA 100/102 CON		

Sheet 1 of 4

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
fw		3,966,808		Luciano	06-29-1976	
		4,961,926		Gabrilove	10-09-1990	
		5,082,653		Pan et al.	01-21-1992	
		5,102,870		Florine et al.	04-07-1992	
		5,284,963		Sum et al.	02-08-1994	
		5,328,902		Sum et al.	07-12-1994	
		5,386,041		Sum et al.	01-31-1995	
		5,401,729		Sum et al.	03-28-1995	
		5,420,272		Sum et al.	05-30-1995	
		5,430,162		Sum et al.	07-04-1995	
		5,545,668		Skubitz et al.	08-13-1996	
		5,635,489		Haley	06-03-1997	
		5,827,840		Ramamurthy et al.	10-27-1998	
		5,886,175		Sum et al.	03-23-1999	
		5,945,089		Libin	08-31-1999	
fw		5,981,499		Hau	11-09-1999	
		6,025,326		Steinberg et al.	02-15-2000	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		WO	94/27579	A1	Ribogene, Inc.	12-08-1994		
		WO	98/18610	A1	Bernard Van Lengerich	05-07-1998		
		WO	99/22703	A1	Lurident Ltd.	05-14-1999		
fw		WO	99/45910	A2	Mucosal Therapeutics LLC ✓	09-16-1999		
		WO	00/07601	A1	Advanced Vision Research	02-17-2000		

Examine Signature	<i>Wolman</i>	Date Considered	1/25/02
-------------------	---------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	Continuation of 09/661,836		
		Filing Date	December 4, 2001		
		First Named Inventor	James Ronald Lawter		
		Group Art Unit			
Examiner Name					
Sheet	2	of	4	Attorney Docket Number	ORA 100/102 CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	✓	BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," <i>J Pediatr Hematol Oncol</i> 17(2):151-55 (1995).	
	✓	CARTEE, et al., "Evaluation of GM-CSF mouthwash for prevention of chemotherapy-induced mucositis: a randomized, double-blind, dose-ranging study," <i>Cytokine</i> 7(5):471-7 (1994).	
	✓	CHI, et al., "Effect of granulocyte-macrophage colony-stimulating factor on oral mucositis in head and neck cancer patients after cisplatin, fluorouracil, and leucovorin chemotherapy," <i>J. Clin. Oncol.</i> 13(10):2620-28 (1995).	
		CUTLER & SCHUBERT, "Patient factors affecting <i>Helicobacter pylori</i> eradication with triple therapy," <i>American Journal of Gastroenterology</i> 88(4):505-509 (1993).	
	✓	EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," <i>Int. J. Radiat. Oncol. Biol. Phys.</i> 28(3):693-98 (1994).	
	✓	EPSTEIN, et al., "Benzidamine hydrochloride in prevention and management of pain in oral mucositis associated with radiation therapy," <i>Oral Surg. Oral Med. Oral Pathol.</i> 62(2):145-8 (1986).	
	✓	EPSTEIN, et al., "Prevention of oral mucositis in radiation therapy: a controlled study with benzydamine hydrochloride rinse," <i>Int. J. Radiation Oncology Biol. Phys.</i> 16(6):1571-5 (1989).	
	✓	<i>Essentials of Medicinal Chemistry</i> John Wiley and Sons, Inc., pp 512-517 (1976).	
		FACCHINI, et al., "Attività di flunoxapofene per uso topico nelle vaginiti aspecifiche. Confronto con meclociclina solfosalicilato," <i>Minerva Ginecologica</i> 41(12):609-614 (1989).	
	✓	FERRETTI, et al., "Control of oral mucositis and candidiasis in marrow transplantation: a prospective, double-blind trial of chlorhexidine digluconate oral rinse," <i>Bone Marrow Transplant</i> 3(5):483-93 (1990).	

Examiner's Signature		Date Considered	1/25/02
----------------------	--	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	Continuation of 09/661,836		
		Filing Date	December 4, 2001		
		First Named Inventor	James Ronald Lawter		
		Group Art Unit			
		Examiner Name			
Sheet	3	of	4	Attorney Docket Number	ORA 100/102 CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	✓	FOOTE, et al., "Randomized trial of a chlorhexidine mouthwash for alleviation of radiation-induced mucositis," <i>J. Clin Oncol.</i> 12(12):2630-33 (1994).	
		FRANCESCHI, et al., "Solitary J-pouch ulcer causing pouchitis-like syndrome," <i>Diseases of the Colon and Rectum</i> 29(8):515-517 (1986).	
	✓	LOPRINZI, et al., "Alleviation of cytotoxic therapy-induced normal tissue damage," <i>Sem. Oncol.</i> 22(2) Suppl. 3:95-97 (1995).	
	✓	MITSCHER, et al., "Quinolone antimicrobial agents. 1. Versatile new synthesis of 1-alkyl-1,4-dihydro-4-oxo-3-quinolinecarboxylic acids," <i>J. Med. Chem.</i> 21(5):485-9 (1978).	
		ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," <i>Special Care in Dentistry</i> 10(1):21-25 (1990).	
		SCHENK, et al., "Controlled local delivery of tetracycline HCl in the treatment of periimplant mucosal hyperplasia and mucositis," <i>Clinical Oral Implants Research</i> 8(5):427-433 (1997).	
	✓	SONIS, 1993b, "Oral Complications in Cancer Therapy," In: <i>Principles and Practice of Oncology</i> , De Vitta et al., eds., pp. 2385-2394 (J. B. Lippincott, Philadelphia).	
	J	<i>Special Care in Dentistry</i> Jan.-Feb, pages 21-25 (1990).	
	✓	SPIJKERVET, et al., "Chlorhexidine inactivation by saliva," <i>Oral Surg. Oral Med. Oral Pathol.</i> 69(4):444-49 (1990).	
	✓	VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," <i>Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.</i> 80(1):36-42 (1995).	

Examiner's Signature		Date Considered	1/25/02
----------------------	--	-----------------	---------

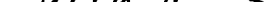
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	Continuation of 09/661,836
				Filing Date	December 4, 2001
				First Named Inventor	James Ronald Lawter
				Group Art Unit	
				Examiner Name	
Sheet	4	of	4	Attorney Docket Number	ORA 100/102 CON

[illegible]

Examiner's Signature		Date- Considered	1/25/02
-------------------------	---	---------------------	---------

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.